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Chronology of a core required study for clothianidin 2003-2010
Beyond Pesticides and Pesticide Action Network North America

Response to EPA's initial media statement on 12.9.10

It is clear the EPA, when issuing a conditional registration for clotlhianidin in 2003 established a requirement for a field study that it considered core and essential to the issuance of the continued registration of the chemical. EPA develops requirements such as these in accordance with guidance when determined necessary. In this case, as EPA stated in 2003, "**The possibility of toxic chronic exposure to nontarget pollinators through the translocation of clothianidin residues in nectar and pollen has prompted EFED to require field testing** (141-5) that can help in evaluating this uncertainty. In order to fully evaluate the possibility of this long term toxic effect, a **complete worker bee life cycle study must be conducted**. . ." At this point, the study requirement became "core" to the registration.

Bayer conducted these studies. EPA accepted Bayer's study in November 2007. In November 2010, however, EPA changed its position on this "core" study in a memorandum "Clothianidin Registration of Prosper T400 Seed Treatment on Mustard Seed and Poncho/Votivo Seed Treatment on Cotton," November 2, 2010 (see pp. 2, 4). In that memo, it is stated that, "A previous field study (MRID 46907801/46907802) investigated the effects of clothianidin on whole hive parameters and was classified as acceptable. However, after another review of this field study in light of additional information, deficiencies were identified that render the study supplemental. **It does not satisfy the guideline 850.3040**, and **another field study is needed to evaluate the effects of clothianidin on bees through contaminated pollen and nectar**." It is clear in that document that the "required" study for "Honey Bee Field Testing for Pollinators" is not acceptable to support the registration of clothianidin, and as a result "more data is needed" (see p27). While the study may contain "some" useful information, as stated by EPA, it does not contain "required" information necessary to registration.

The issue here is not whether one can attribute one pesticide as the cause of colony collapse disorder (CCD). That claim has not been made by anyone. The critical issue is that we know that this is a highly toxic pesticide to bees and, given the EPA's inability to identify the cause(s) of CCD, it must not and does not have the legal authority to allow a pesticide to be used without "required" data that enables the agency to answer this critical question relating to the health of honeybees.

Supporting Documentation

EPA Addendum to February 2003 Risk Assessment...PAGE 2

"Since this compound is persistent (field dissipation ½ life = 277 – 1,386 days), toxic to honeybees, and has the potential for expression in pollen and nectar of flowering crops, EFED also concluded that there was a potential for long term toxicity to these pollinators. **The**

possibility of toxic chronic exposure to nontarget pollinators through the translocation of clothiandin residues in nectar and pollen has prompted EFED to require field testing (141-5) that can help in evaluating this uncertainty. In order to fully evaluate the possibility of this long term toxic effect, a **complete worker bee life cycle study must be conducted**, as well as an evaluation of exposure to the queen. Because of this concern, EFED suggested that the following honeybee label statement be included:

> *This compound is toxic to honey bees. The persistence of residues and the expression of clothianidin in nectar and pollen suggests the possibility of chronic toxic risk to honey bee larvae and the eventual stability of the hive.*
>
> However, after further consideration, EFED would like to suggest that the registrant be given conditional registration that is contingent on their conducting the chronic honey bee study that evaluates the sublethal effects of clothianidin to the hive over time. EFED will therefore defer the requirement for this bee labeling statement until after the chronic study has been reviewed."

November, 2007 EPA memo…PAGE 5

In its memo entitled "Review of Data Package DP336888 for Clothianidin," EPA accepted the following study: Cutler, C. 2006. An Investigation of the Potential Long Term Impact of Clothianidin Seed Treated Canola on Honey Bees, Apis mellfeva L. Laboratory Report JD: 2005-CSD-EBTIX064. MRID 46907801 (with addendum 46907802). According to the memo,

> "This study was submitted to provide data on the toxicity of clothianidin to honeybees in a field test for the purpose of chemical registration (new use). Specifically, the test was conducted in response to a request by the Canadian PMRA and the U.S. EPA; as a condition for Poncho@ registration in these countries, Bayer
> Cropscience was asked to investigate the long-term toxicity of clothianidin-treated canola to foraging honey bees."

November, 2010 EPA memo...PAGE 2

"A previous field study (MRID 46907801/46907802) investigated the effects of clothianidin on whole hive parameters and was classified as acceptable. However, after another review of this field study in light of additional information, deficiencies were identified that render the study supplemental. **It does not satisfy the guideline 850.3040**, and **another field study is needed to evaluate the effects of clothianidin on bees through contaminated pollen and nectar**. Exposure through contaminated pollen and nectar and potential toxic effects therefore remain an uncertainty for pollinators."

November, 2010 EPA memo...PAGE 27

Table of Ecological Toxicity Data Requirements

Guideline	Date Requirement	MRID #	Classification	Is more data needed ?

850.304	Honey Bee Field Testing for Pollinators	45422431	Supplemental	
		45422432	Supplemental	
		45422433	Supplemental	
		45422435	Supplemental	
		45422436	Supplemental	
		45422437	Supplemental	
		45422440	Supplemental	
		46907801/46907802	Supplemental	Yes

November, 2010 EPA memo...PAGE 4

"Field Test for Pollinators (850.3040): The possibility of toxic exposure to nontarget pollinators through the translocation of clothianidin residues that result from seed treatments has **prompted EFED to require field testing (850.3040)** that can evaluate the possible chronic exposure to honey bee larvae and queen. In order to fully evaluate the possibility of this toxic effect, a field study should be conducted and the protocol submitted for review by the Agency prior to initiation. Another study had been submitted to satisfy this guideline requirement. While it had originally been classified as acceptable, after recent reevaluation it is classified as supplemental, and a field study is still being needed for a more refined risk assessment."